

Advisory Commission on Childhood Vaccines (ACCV)

Food and Drug Administration Update

September 6, 2019



CDR Valerie Marshall, MPH, PMP

Immediate Office of the Director

Office of Vaccines Research and Review (OVRR)

Center for Biologics Evaluation and Research (CBER)

Food and Drug Administration (FDA)

Influenza Vaccine Strain Changes

- The FDA approved supplements for the Biologics License Applications (BLA) for seasonal influenza vaccines to include the 2019-20 United States formulation and associated labeling revisions.

Upcoming Workshop

- On September 16-17, 2019, the Center for Biologics Evaluation and Research, the National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIAID), and the Coalition for Epidemic Preparedness Innovations (CEPI) will hold a public workshop entitled, **“Identification and Use of Biomarkers to Advance Development of Preventive Vaccines”**
- The public workshop will bring together government agencies, academia, industry, and other stakeholders to discuss the scientific, clinical, and regulatory challenges encountered in the identification, characterization, and qualification of biomarkers for preventive vaccines for infectious diseases indications.
- The workshop will include discussions on exploring the use of biomarkers to inform the clinical development of preventive vaccines and in regulatory decision making.

Registration for Workshop

- To register for the public workshop, please visit the following website:
<https://www.eventbrite.com/e/identification-and-use-of-biomarkers-to-advance-development-of-preventive-vaccines-public-workshop-tickets-61166762433>



Thank you!

